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USA**8. 510 (k) Summary****Submitter :**

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Contact Person:

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Product Name:

Proprietary Name: OSOM™ Strep A Test
Common Name: Rapid Immunoassay for Group A Streptococcal
Antigen Test Kit
Classification Name: Antigens, All Groups, Streptococcus spp.

Intended Use:

OSOM Strep A Test is an immunochromatographic assay for the qualitative detection of Group A Streptococcal antigen from throat swabs or confirmation of presumptive Group A Streptococcal colonies from culture.

Description:

OSOM Strep A Test uses color immunochromatographic dip stick technology with antibodies coated on the membrane. If group A Streptococcus is present in the swab sample, a blue test line will appear to indicate a positive result.

Substantial Equivalence:

The OSOM Strep A Test is substantially equivalent to results obtained through isolation of Group A Streptococcus colonies on sheep blood agar medium followed by a serological grouping of presumptive Group A Streptococcus. Serotyping is used to confirm identity of presumptive Group A Streptococcus isolates.

These techniques and OSOM Strep A are substantially equivalent in that:

- a. Both are intended for use in the detection of Group A Streptococcus.
- b. Both are *in vitro* tests.

The tests differ in that:

- a. OSOM Strep A can detect non-viable as well as viable organisms.
- b. Results can be obtained in minutes using OSOM Strep A test. Culture methods to obtain comparable results require 18-24 hours or longer.

Applicant Signed: SL. Cheng Date: April 11, 1996
Shu-Ching Cheng